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*Admitted only in Maryland
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•Practice Limited to
Federal Agencies

March 1, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Application No. 10/630,896; Filed: July 31, 2003
For: **Aryl Substituted Benzimidazoles and Their Use as Sodium Channel Blockers**
Inventors: SUN *et al.*
Our Ref: 1861.1520001/JMC/RHD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement;
3. 7 pages of Form PTO-1449 citing 37 documents;
4. Copies of 28 documents; and
5. One (1) return postcard.

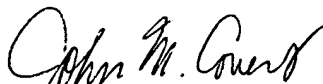
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
March 1, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert
Attorney for Applicants
Registration No. 38,759

JMC/RHD:cpn



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Sun *et al.*

Appl. No. 10/630,896

Filed: July 31, 2003

For: **Aryl Substituted
Benzimidazoles and Their Use
as Sodium Channel Blockers**

Confirmation No. 9619

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1861.1520001/JMC/RHD

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AK1** and **AA2** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states “[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003.” A copy of each other document is included.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants’ undersigned representative submits the following, in regards to non-English language documents **AL1** and **AO1** cited on Form PTO 1449:

Document **AL1**, European Patent Publication No. EP 0 639 573 A1, is in the German language. An English language abstract of document **AL1** is attached as document **AS6**.

Document **AO1**, Japanese Patent Publication No. JP 2000323278, is in the Japanese language. An English language abstract of document **AO1** is attached as document **AT6**.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Application No. 10/628,487, Sun *et al.*, filed July 29, 2003, and submitted herewith;

U.S. Application No. 10/630,763, Sun, Q. and Kyle, D.J., filed July 31, 2003, and submitted herewith; and

U.S. Application No. 10/630,814, Sun, Q. and Kyle, D.J., filed July 31, 2003, and submitted herewith.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

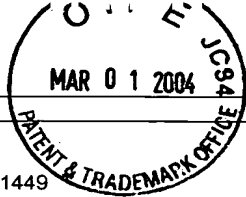
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert
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Date: Mar. 1, 2004
1100 New York Avenue, N.W.
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(202) 371-2600



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1861.1520001/JMC/RHD

APPLICATION NO.
10/630,896

FIRST NAMED INVENTOR
Sun *et al.*

FILING DATE
July 31, 2003

ART UNIT
To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	6,211,177 B1	04/03/2001	Sperl <i>et al.</i>			11/24/1998
	AB1	6,335,354	01/01/2002	Hogenkamp			03/29/2001
	AC1	2002/0006947 A1	01/17/2002	Hogenkamp <i>et al.</i>			03/22/2001
	AD1	2002/0022624 A1	02/21/2002	Dinnell <i>et al.</i>			07/11/2001
	AE1	2002/0040025 A1	04/04/2002	Hogenkamp <i>et al.</i>			03/12/2001
	AF1	6,414,011	07/02/2002	Hogenkamp <i>et al.</i>			03/24/2000
	AG1	2003/0055088 A1	03/20/2003	Shao <i>et al.</i>			09/06/2002
	AH1	2003/0069292 A1	04/10/2003	Hogenkamp <i>et al.</i>			04/30/2002
	AI1	2003/0073724 A1	04/17/2003	Shao <i>et al.</i>			09/06/2002
	AJ1	2003/0109521 A1	06/12/2003	Sun <i>et al.</i>			07/16/2002
	AK1	2003/0236273 A1	12/25/2003	Goehring <i>et al.</i>			03/13/2003

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 639 573 A1 ✓	02/22/1995	Germany			Yes X No
	AM1	WO 98/08818 ✓	02/25/1999	WIPO			Yes No
	AN1	WO 99/43672 ✓	02/09/1999	WIPO			Yes No
	AO1	JP 2000-323278 ✓	11/24/2000	Japan			Yes X No
	AP1	WO 01/21634 ✓	03/29/2001	WIPO			Yes No

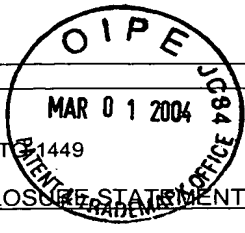
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Bensimon, G., <i>et al.</i> , "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," <i>New Engl. J. Med.</i> 330:585-591, Massachusetts Medical Society (1994)
AS	1	Brown, C.M., <i>et al.</i> , "Neuroprotective properties of lifarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," <i>British J. Pharmacol.</i> 115:1425-1432, Stockton Press (1995)
AT	1	Catterall, W.A., "Neurotoxins that Act on Voltage-Sensitive Channels in Excitable Membranes," <i>Ann. Rev. Pharmacol. Toxicol.</i> 20:15-43, Annual Reviews, Inc. (1980)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PT 31449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1861.1520001/JMC/RHDAPPLICATION NO.
10/630,896FIRST NAMED INVENTOR
Sun *et al.*FILING DATE
July 31, 2003ART UNIT
To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	2004/0002523 A1	01/01/2004	Hogenkamp <i>et al.</i>			06/09/2003
	AB						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 01/83472 ✓	11/08/2001	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

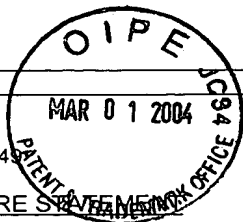
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," <i>Science</i> 242:50-61, American Association for the Advancement of Science (1988)
	AS	2	Catterall, W.A., "Common modes of drug action on NA ⁺ channels: local anesthetics, antiarrhythmics and anticonvulsants," <i>Trends Pharmacol. Sci.</i> 8:57-65, Elsevier Science Publishers (1987)
	AT	2	Denicoff, K.D., <i>et al.</i> , "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," <i>J. Clin. Psychiatry</i> 55:70-76, Physicians Postgraduate Press (1994)

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	AA						
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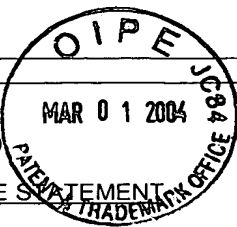
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Donaldson, I., "Tegretol: A double blind trial in tinnitus," <i>J. Laryngol. Otol.</i> 95:947-951, Journal of Laryngology and Otology Ltd. (1981)
	AS	<u>3</u>	Graham, S.H., <i>et al.</i> , "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion," <i>J. Pharmacol. Exp. Ther.</i> 269:854-859, The American Society for Pharmacology and Experimental Therapeutics (1994)
	AT	<u>3</u>	Majumdar, B., <i>et al.</i> , "An electrocochleographic study of the effects of lignocaine on patients with tinnitus," <i>Clin. Otolaryngol.</i> 8:175-180, Blackwell Scientific Publications (1983)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

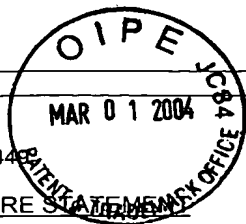
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Mane, D.V., <i>et al.</i> , "Synthesis and biological activity of some new 2-alkyl-1-(1'-dihydropyridylmethyl)benzimidazoles," <i>Indian J. Chem.</i> 34B:917-919, The Council of Scientific & Industrial Research (1995)
	AS	<u>4</u>	Moller, A.R., "Similarities Between Chronic Pain and Tinnitus," <i>Am. J. Otol.</i> 18:577-585, American Journal of Otology, Inc. (1997)
	AT	<u>4</u>	Simpson, J.J., and Davies, W.E., "Recent advances in the pharmacological treatment of tinnitus," <i>TIPS</i> 20:12-18, Elsevier Science (1999)

EXAMINER

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FORM PTO-144

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1861.1520001/JMC/RHD
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Sun *et al.*
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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	AO						Yes No
	AP						Yes No

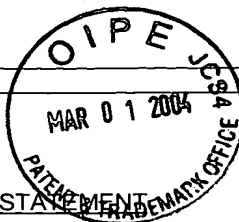
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Srivastava, A.J., <i>et al.</i> , "Synthesis and Antiviral Activity of Mannich Bases of 2-[(2-Oxo-4-Methyl-7-HydroxyQuinoliny)-1-(4'-aryl)] Benzimidazole," <i>Indian Drugs</i> 28:75-77, Indian Drug Manufacturers' Association (1990)
	AS	<u>5</u>	Stys, P.K., <i>et al.</i> , "Ionic Mechanisms of Anoxic Injury in Mammalian CNS White Matter: Role of Na ⁺ Channels and Na ⁺ -Ca ²⁺ Exchanger," <i>J. Neurosci.</i> 12:430-439, Society for Neuroscience (1992)
	AT	<u>5</u>	Taylor, C.P., and Meldrum, B.S., "Na ⁺ channels as targets for neuroprotective drugs," <i>Trends Pharmacol. Sci.</i> 16:309-316, Elsevier Science Ltd. (1995)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1861.1520001/JMC/RHD
FIRST NAMED INVENTOR
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	AN						Yes No
	AO						Yes No
	AP						Yes No

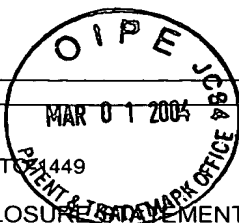
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Tonndorf, J., "The analogy between tinnitus and pain: A suggestion for a physiological basis of chronic tinnitus," <i>Hear. Res.</i> 28:271-275, Elsevier Science Publishers (1987)
	AS	<u>6</u>	English language abstract of EP 0 639 573 A1, Derwent World Patents Index (Dialog File 351), WPI Accession No. 10182147
	AT	<u>6</u>	English language abstract of JP 2000323278, Derwent-World Patents Index (Dialog File 351), WPI Accession No. 13736273

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO 449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1861.1520001/JMC/RHDAPPLICATION NO.
10/630,896FIRST NAMED INVENTOR
Sun *et al.*FILING DATE
July 31, 2003ART UNIT
To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>7</u>	International Search Report for PCT Application No. PCT/US 03/23828, mailed on January 20, 2004, European Patent Office, Netherlands
	AS		
	AT		

EXAMINER

DATE CONSIDERED

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